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Airport Industrial Park
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Sponsor: Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, IN 46581-0578

Device: Advantage[®] MAPF[®] Hip Femoral Component

Classification Name: Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented (KWY)

Indications for Use: Single use, cemented or press-fit hip replacement component for use in patients requiring joint replacement due to trauma, disease or failed previous hip replacement surgery.

Device Description: The Advantage MAPF Femoral Component is a cobalt alloy (Co-Cr-Mo) femoral stem which is designed to articulate with any commercially available acetabular component. It has no linkage across the joint.

The MAPF devices are straight, as apposed to anatomic or curved in design. This eliminates the need for left and right configurations thus reducing the cost of inventory to the hospital. The I-beam distal geometry increases the strength and flexibility of the device. The lateral edge of the device is straight which enables the surgeon to rasp and seat the prosthesis, without creating a gap in the proximal lateral aspect of the femur. A lateral fin provides rotational stability. The duckbill type collar prevents subsidence.

Available in 6 sizes (diameters) for easier patient matching, all sizes are 160mm in length with a neck length of 32mm. Because this device is usually used in the older, low demand patient, it would most often be used in conjunction with a bipolar or endoprosthetic head.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to the bone cement	Blood vessel damage	Bone fracture
Deformity of the joint	Soft tissue imbalance	Infection
Cardiovascular disorders	Delayed wound healing	Hematoma
Fracture of the cement	Metal sensitivity	Dislocation
Implant loosening/migration	Fracture of the components	Excessive wear
Breakdown of the porous surface	Tissue growth failure	Nerve damage

Substantial Equivalence: In function and overall design, the Advantage MAPF Femoral Components are equivalent to almost all hip components on the market. These stems include:

Moore Type Stem (Meditec)
APF Moore-Type Femoral Stem (3M)
Advantage MAPF Hip System (Kirschner)
Ranawat/Burstein Hip System (Biomet, Inc)